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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,282	06/18/2001	Bonnie M Davis	U013469-7	6731

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26 WEST 61ST STREET
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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/14/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Appli ation No.

09/856,282

Applicant(s)

DAVIS, BONNIE M

Examiner

Dwayne C Jones

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-- Th MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-40 are pending.
2. Claims 1-40 are rejected.

Response to Arguments

3. Applicant's arguments filed May 23, 2002 have been fully considered but they are not persuasive. Applicant argues that the instantly claimed acetylcholinesterase inhibitor which is formulated to delay its activity for a predetermined period is not rendered obvious over Shapiro in view of Conte et al. and Brossi et al. in view of Conte et al. Applicant also argues that Conte et al. is directed to administering pharmaceuticals, which depend on circadian rhythmicity.
4. Applicant argues that the prior art references of Shapiro and Brossi et al. do not provide one having ordinary skill in the art with the motivation to delay or protract the action of the active materials to which they refer. Although this allegation is true, when Shapiro and Brossi et al. are combined with the teachings of Conte et al., the skilled artisan is provided with motivation to administer pharmaceuticals in a protracted and time-released manner. In fact, Conte et al. state that "in the pharmaceutical field many successful efforts have been made for the development and production of rate-controlled delivery devices, (see column 1, 1st paragraph, page 1017).
5. In addition, applicant argues that Conte et al. is directed to administering pharmaceuticals, which depend on circadian rhythmicity and accordingly there is no suggestion that drugs for treatment of conditions other than circadian rhythmicity. The

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prior art reference of Conte et al. does provide clear motivation to the skilled artisan to develop and administer pharmaceuticals and drugs in a time-released manner, (see column 1, 1st paragraph, page 1017). One having ordinary skill in the art would have found it obvious in view of Shapiro and Brossi et al. to make pharmaceuticals, such as acetylcholinesterase inhibitors, in a formulation which would delay its activity for a predetermined period with the teachings of Conte et al., especially when Conte et al. do specifically state that "in the pharmaceutical field many successful efforts have been made for the development and production of rate-controlled delivery devices, (see column 1, 1st paragraph, page 1017).

6. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the acetylcholinesterase inhibitors of galanthamine and lycoramine as well as the instantly described analogs of these compounds, does not reasonably provide enablement for other compounds which are known as acetylcholinesterase inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. All questions of enablement are evaluated against the claimed subject matter. The question asked by one skilled in the art is whether everything within the scope of the claim is enabled. The instant claims cover all compounds having the pharmaceutical property of being known descriptively as inhibitors of acetylcholinesterase. Accordingly, the instant specification only provides guidance and support for the acetylcholinesterase inhibitors as embraced by galanthamine and lycoramine as well as their analogs. The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). One does not look to the claims but to the specification to find out how to practice the invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-7 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). Due to the unpredictability in the art, the state of the art and the lack of working examples for compounds other than those galanthamine and lycoramine as well as their analogs, one skilled in the art is subjected to an undue experimentation in order to

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determine the other compounds which are supported by the pharmaceutical property of being known as acetylcholinesterase inhibitors.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Moormann of U.S. Patent No. 5,643,905. Moormann teaches of the administration of galanthamine, which is an inhibitor of cholinesterase. Moormann also teach of administered in a controlled release form, (see column 2, lines 1-8 and lines 33-37).

11. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Opitz of U.S. Patent No. 5,519,017. Opitz teaches of the administration of galanthamine in a controlled release form, (see column 1, lines 10 and 11 and column 2, lines 17, 18 and 22-45).

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

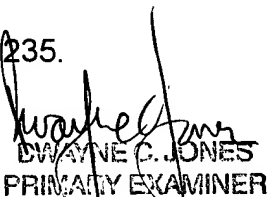
13. The rejection of claims 1-40 under 35 U.S.C. 103(a) as being unpatentable over is maintained for both the above-stated and reasons of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
August 9, 2002